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| 10/766,912 | 01/30/2004 | Carl Ernest Alexander | 4506-1025 | 2239 |

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YOUNG & THOMPSON
209 Madison Street
Suite 500
Alexandria, VA 22314

| EXAMINER | |
|---|---|
| ROBERTS, LEZAH | |
| ART UNIT | PAPER NUMBER |
| 1612 | |

| NOTIFICATION DATE | DELIVERY MODE |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

| Office Action Summary | Application No. | Applicant(s) |
|---|---|---|
| | 10/766,912 | ALEXANDER ET AL. |
| | Examiner | Art Unit |
| | LEZAH ROBERTS | 1612 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 June 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) *1,3,4,7,8,10,11,13,18,23-29,31,35 and 36* is/are pending in the application.

4a) Of the above claim(s) *10,11,18,29 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7,8,13,23-28,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

# DETAILED ACTION

Applicants' arguments, filed June 2, 2011, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

## *Claims*

**Claim Rejections - 35 USC § 112 - New Matter (New Rejection)**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4, 7, 8, 13, 23-28, 35 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the

limitations "water between 32% to 35% by weight" in claim 1 and “water at between 13.9% and 43.1% by weight” in claim 23. The instant specification or the originally filed claims do not appear to support this limitation. Therefore the limitation is considered “New Matter".

**Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejections)**

1) Claims 3, 4, 24, 25 and 28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bolten et al. (US 4,814,179) as evidenced by Athanikar (US 6,379,651) as applied to claims 1, 7, 8, 13, 23, 27, 30 and 34. The rejection is maintained and further applied to claims 1, 7, 8, 13, 23, 27, 35 and 36.

Bolton et al. disclose sustained release gel tablets. The compositions comprise a gelling agent, oil, a therapeutic agent and water (Abstract). Therapeutic agents include analgesics and tetracycline, which may be used in the treatment of dental conditions (as evidenced by Athanikar US 6,379,651). The gelling agent comprises 0.5 to 4% of the gel tablet and includes agar and carageenan (col. 4, lines 1-13), encompassing instant claims 1, 30 and 34. The tablets are made by 1) preparing a solution of the hydrocolloid gelling agent and excipients, if any, in hot water; 2) preparing a mixture of a therapeutic agent and a therapeutically acceptable inert oil; 3) cooling the solution of gelling agent, but not to the point where gelation takes place, and combining the solution and the mixture from step (2) with stirring, while maintaining the temperature above the gelation temperature; 4) pouring the mixture from step (3) into a tablet mold and allowing it to

stand in the mold to form a gel; and 5) drying the molded gel tablets to reduce the water content, encompassing claim 1, 23 and 30. The Example 9 comprises ampicillin (an antibiotic used in dental compositions to treat conditions of the oral cavity, as evidenced by Athanikar US 6,379,651, col. 5, 46-55), agar and water, and the tablet has a final mass of about 423 mg, encompassing claims 1, 8, 27 and 30. The compositions may also comprise conventional additives and excipients such as surfactants, preservatives, bulking agents and antioxidants (col. 4, lines 28-30).

The instant specification discloses that similes for the term “bead” includes tablet (page 3, paragraph 5). Therefore the disclosure of a gel tablet in Bolten et al. reads on the recitation of "gel bead" by the instant claims.

In regard to the gel framework breaking apart, this appears to be based on the amount of gelling agent used. The reference discloses the gelling agent comprises 0.5 to 4% of the gel tablet and the claims recite 0.5 to 1.2%. Thus the gel tablet should have the property of breaking apart when disrupted by a person in a personal oral or dental procedure.

In regard to claim 7, the compositions comprise actives that are used in dental care, such as ampicillin, and may also comprise surfactants. Therefore the reference meets the limitation of the bead comprising a dentifrice.

The reference differs from the instant claims insofar as it does not disclose the end points recited in claims 3, 4, 24, 25 and 28.

The prior art does not disclose the exact claimed values of 0.1 to about 2 percent as recited in claim 3, 0.3 to about 0.95 as recited in claim 4, 0.1% by weight to 2% by weight as recited in claim 24, 0.3% by weight to 0.95% by weight as recited in claim 25, and 0.7 percent by weight to 0.9 percent by weight as recited in claim 28 but does overlap disclosing 0.5 to 4%: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

## ***Response to Arguments***

*Applicant's Arguments*

Applicant argues that none of the applied references, whether considered individually or in combination, teaches or suggests a gel bead having a water content as recited in amended claims 1 and 23. On the contrary, BOLTON recites a water content of approximately 4.6%. The tablets are intended to reach the stomach and perform a slow release while floating in the gastric juice. Although the examples such as at column 5 and column 6 disclose around 40 to 55% water during a manufacturing stage, BOLTON's finished product pertinent to the invention claimed is a dried tablet with a water content of 4.6 % (column 6, line 24). Hence, BOLTON does not disclose a gel bead with a water content as recited by claims 1 and 23. ATHANIKAR does not teach

water content in the claimed range.

*Examiner's Response*

It is noted that Bolton does disclose a water content when dry of 4.6%. However, it is also noted that the claims as recited encompass wet and dry compositions and therefore would encompass tablets before they are dried, while they are being dried and when dried. In other the words, the claims include tablets in the manufacturing stage as well as finished products. Further the water content before the tablet is dried is 45%. Therefore it is reasonable to conclude that during the drying process that amount of water would be in the range of between 32% to 35% because the water content goes from 45% before drying to 4.6% after drying. Further the claims of Bolton recite the composition comprise "gelling agent, 0.5 to 4%; oil, 10 to 20%; therapeutic agent, 50 to 75%; [and] the balance water". Therefore water may comprise 1% to 39.5% water based on the percentages of the other components. The prior art does not disclose the exact claimed values of between 32% to 35% water as recited in claim 1 and between 13.9% and 43.1% water recited in claim 23 but does overlap disclosing 1% to 39.5%: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore the amount of water in the claims is obvious over the amount disclosed by the reference, thus, meeting the limitation of the instant claims including the amounts of new claims 35 and 36.

2) Claim 26 was rejected under 35 U.S.C. 103(a) as being unpatentable over Bolten et al. (US 4,814,179) as evidenced by Athanikar (US 6,379,651) as applied to claims 1, 3, 4, 7, 8, 13, 23-25, 27, 28, 30 and 34 above, in further view of Huang et al. (US 6,485,738). The rejection is maintained.

Bolten et al. as evidenced by Athanikar is discussed above and discloses that the gel tablets may be used to deliver vitamins. The tablet also comprises oil and therapeutic agents (Abstract). The reference differs from the instant claim insofar as it does not disclose the compositions comprise gelatin.

Huang et al. disclose gel delivery compositions for promoting bioavailability of vitamins (Abstract). Agar is preferred to pectin because its smaller molecular structure helps in absorption of the delivered component. The gelatin/agar base provides a flexible base that can cover a full range of consistencies, from spoonable suspension to a rigid gel. The base provides a stable environment for both water and lipid soluble substances. The bioavailability enhancing substance is preferably a surfactant such as a mixture of lecithin and Vitamin E which promotes absorption of the carried substance. Other ingredients, such as flavoring agents, coloring agents or thickeners, among others, can be incorporated in the present invention (col. 2, lines 6-15). Components such as calcium glycerophosphate are used and reduce dental caries (col. 5, lines 65-

67). Ingredients such as drugs may also be incorporated into the gels (col. 5, lines 9-12). The ratio of agar to gelatin varies form 0.5 to 1 to 2.5 to 1 (col. 7, line 33-35).

The reference differs from the instant claim insofar as it does not disclose the recited amounts of agar and gelatin nor does it disclose the gels are beads that break apart, although it does disclose the compositions may be rigid gels.

It would have been obvious to one of ordinary skill in the art to have added gelatin to the compositions of Bolten et al. comprising agar, motivated by the desire to formulate a base for the gel tablet that provides a stable environment for both water and lipid soluble substances, as disclosed by Huang et al.

Bolten et al. disclose the amount of gelling agent ranges from 0.5 to 4% by weight. Huang et al. disclose the ratio of agar to gelatin ranges from 0.5:1 to 2.5:1, which would encompass 0.2 to 8% by weight of gelatin calculated from the amount of gelling agent when used in the compositions of Bolten et al. and the ratio disclosed by Huang et al. The prior art does not disclose the exact claimed values of 1% by weight to 4% by weight gelatin but does overlap disclosing 0.2% to 8% (based on the above ratio): in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

## ***Response to Arguments***

*Applicant's Arguments*

HUANG also fails to teach this feature (the amount of water). HUANG is directed to provide a slow release gel that carries the active ingredients to the small intestine. Water content is disclosed as between 1% and 20% as best understood (see, e.g., table in column 6) depending on the combination selected. The range of water content disclosed by HUANG is far less than the presently claimed range.

*Examiner's Response*

As asserted by Applicant above, Huang discloses that the amount water ranges from 1% to 20%, which overlaps the range recited by instant claim 23 (water at between 13.9% and 43.1% by weight) from which 26 depends. Therefore the water content disclosed by Huang is not far less than the presently claimed range and the range of the instant claim is obvious over the range of Huang.

**Obvious-Type Double Patenting**

Claims 1, 3, 4, 7, 8, 13, 23-28, 30 and 34 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 17 of copending Application No. 12/067817. The rejection is maintained and further applied to claims 35 and 36. Claims 30 and 34 are cancelled.

Applicant argues the provisional rejection is noted and no Terminal Disclaimer is required at this time.

This rejection is maintained pending appropriate action by applicant.

Claims 1, 3, 4, 7, 8, 13, 23-28, 35 and 36 are rejected.

Claims 10, 11, 18, 29 and 31 are withdrawn.

No claims allowed.

## *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612
/Gollamudi S. Kishore/
Primary Examiner, Art Unit 1612